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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/942,583      | 08/31/2001  | Andrew Robinson      | 1581.0840001/RWE    | 9616             |

26111 7590 05/08/2003

STERNE, KESSLER, GOLDSTEIN & FOX PLLC  
1100 NEW YORK AVENUE, N.W.  
WASHINGTON, DC 20005

[REDACTED] EXAMINER

MINNIFIELD, NITA M

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1645

DATE MAILED: 05/08/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |                 |
|------------------------------|-----------------|-----------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)    |
|                              | 09/942,583      | ROBINSON ET AL. |
| Examiner                     | Art Unit        |                 |
| N. M. Minnifield             | 1645            |                 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 27 February 2003.

2a) This action is FINAL.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) 9-18, 20 and 21 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-8 and 19 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 9-18, 20 and 21 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892) 4 sheets

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicant's election of Group I, claims 1-8 and 19, in Paper No. 8 (filed February 27, 2003) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 9-18, 20 and 21 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8. *OK*
3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in United Kingdom (9904028.9 UK) on 2/22/99, in United Kingdom (9922561.7 UK) on 9/23/99 and PCT/GB00/000624 on 2/22/00. It is noted, however, that applicant has not filed a certified copy of the UK and GB applications as required by 35 U.S.C. 119(b). *OK*
4. The effective filing date of the present application (09/942583) is 8/31/01. *OK*
5. The disclosure is objected to because of the following informalities: p. 3, l. 37, "aginast", misspelled word; p. 20, l. 26, "expressed two of foreign antigens", this is confusing; p. 39, there is no complete reference citation for Cadieux et al *OK*

1999. Please review specification, there may be other errors. Appropriate correction is required.

6. The use of trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

OK

7. Claims 1-8 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in the recitation of the "composition". What does the composition comprise? The preamble does not indicate/recite what the composition should contain such that one of ordinary skill in the art would know that the method of preparing the composition had been achieved. What is the "immunogenic component or extract"? Is it the expressed heterologous gene product or some protein/antigen from Neisseria? Is the "immunogenic component or extract" some cell component, OMP, LOS, extracted cell components, one antigen, or a group of polypeptides or antigens? What is the "heterologous gene product"? Is it from a non-Neisserial organism or a pathogenic Neisseria organism? Claims 3 and 4 are vague and indefinite in the recitation of "fragment thereof"; what are the metes and bounds? Further, with regard to claim 3, is the "gene or a fragment

thereof from a pathogenic Neisseria" the same as the "gene coding for a heterologous gene product" recited in part a) of claim 1? The same applies to claim 4; are the proteins from N. meningitidis (for example transferring binding protein) supposed to be the heterologous gene product? Claims 6-8 are vague and indefinite in the recitation of the "molecular weight"; how is this determined? With regard to claim 7, does Applicant intend a molecular weight range of 40 kDa to 90 kDa? The recitation of "at least 40 kDa would mean a lower limit of 40 kDa however, "up to 90 kDa" means any molecular weight from 0 kDa to 90 kDa. Claims 5-8 are confusing with regard to the molecular weights recited. The claims recite "50 kDa or lower", "at least 40 kDa and up to 90 kDa" and "at least 80 kDa". However, the specification, at pages 5 and 6, recites "less than 50 kDa, 40-70 kDa and >60 kDa" and "50 kDa or lower, at least 40 kDa and up to 70 kDa and at least 60 kDa". Example 5 of the specification refers to "<40 kDa, 40-67 kDa and >60 kDa". Are these recitations intended to be the same? How were the molecular weights determined? Were the molecular weights determined by the same procedure in each situation?

8. No claims are allowed.
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is

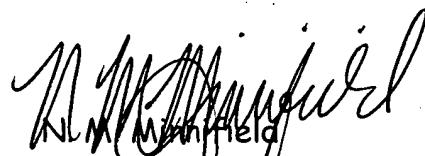
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703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
N.M. Minfield  
Primary Examiner  
Art Unit 1645

NMM  
April 30, 2003